

SPL Process ER/DL Meeting

Meeting Minutes

Oct 8, 2014

Chair of today's meeting: Pat Cowall

Teleconference information:

USA Toll-Free 866-213-2145

USA Paid/International: 609-454-9913

Access code: 273 8216

Teleconference information: How to mute/unmute

#6: Mute

*6: Unmute

Link to the SPL wiki:

<http://spl-work-group.wikispaces.com/share/view/51351516>

Agenda:

1. Business operations qualifiers: additional requirements being added to the operations section in establishment registration (Herb O'Brien and Ruth Kirkner)
<http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/ucm321788.htm>

Business Operation Qualifier

NCI Thesaurus OID: 2.16.840.1.113883.3.26.1.1

NCI concept code for business operation qualifier: C101885

SPL Acceptable Term	Code
Compounding from bulk ingredient	C112092
Compounding sterile products	C112094
Distributes human prescription drug products	C111077
Distributes human over-the-counter drug products	C111078
Intent to compound 506E (drug shortage) drugs	C112087
Manufactures animal prescription drug products	C114889
Manufactures animal over-the-counter drug products	C114891
Manufactures animal over-the-counter Type A medicated article drug products	C114892
Manufactures human over-the-counter drug products	C106645
Manufactures human prescription drug products	C106643
Manufactures Non-Generics	C101886
Manufactures veterinary feed directive Type A medicated article drug products	C114890
No intent to compound 506E (drug shortage) drugs	C112091
Not compounding from bulk ingredient	C112093
Not compounding sterile products	C112095

Meeting Discussion:

As of October 1 the establishment registrations can be submitted for 2015. In order for the submissions to pass, business operation qualifiers need to be included in the ER SPL file. Our software is not up to date and we are using a work around to facilitate the inclusion of this coding in our submissions.

6.1.7 Business Operation Qualifier

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<performance> <actDefinition> ... <subjectOf> <approval> <code code="Qualifier Code" codeSystem="2.16.840.1.113883.3.26.1.1" displayName="Qualifier Display Name" /> </approval> </subjectOf>
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Pages 108 – 109 of Implementation and Validation Guide issued in late August.

The work-around is uploading our xml file (created in our software) to the SPL XForms, adding the business operation qualifier, saving the document and then submitting it through the FDA ESG.

- Until yesterday, the Pragmatic Validator tool was not updated to accept these qualifiers. It is now working.
- The CDER Direct software had glitches initially, but has now been corrected as well.
- We don't remember getting an official separate notification of the implementation of this requirement for operations other than compounding. Per the January IG, we knew they were to be needed for compounding operations, but manufacturing operations were not included. It is in the August IG, and we are not getting validation errors.
- These need to be added to all establishments, and they are part of the current validation procedures.
- For every business operation, you need to put in at least one – can be more -- qualifier.
- The qualifiers in the list are used for both DER and for NDC labeler code (optional)
- These qualifiers are for the benefit of inspectors. So that when they are inspecting, they know what they need to inspect for.
- For more information about which qualifiers are used where, look at the IG – section 6.1.7.
- You should be able to use CDER direct and Xforms. Validator lite has been fixed too.

2. Drug listing – multiple establishments using the same NDC. Mary Beth Kline

- Two establishments are marketing the same drug product but with their own label and NDC number.
- Both establishment's drug listings on DailyMed refer to the same NDA number (that one of the establishments 'own') and both marketing categories are 'NDA'.
- Question - Can only one of the establishments submit both drug listings of the labels and NDCs or does each establishment have to submit their own drug listing? Shouldn't one of the establishments marketing category be 'PLD' and not 'NDA' ?

Meeting Discussion:

- Both labelers have to submit SPL. One establishment can submit both SPLs – the establishment who submits the SPL has to be listed as the registrant within the SPLs.
- But there should be an agreement between the parties – with official agreement or contracts should reflect the agreement.

3. NDC and drug listing questions- dietary supplements: Mary Beth Kline Are NDCs and drug listing required on dietary supplements?

Meeting Discussion:

- Dietary supplements: not required
- See Section 3.2 in the Implementation Guide

4. NDC and drug listing questions- nothing changed : Mary Beth Kline
If nothing changes with the drug product's drug listing information, do we still need to submit yearly to update the version number and date?

Meeting Discussion:

- DER have to be submitted annually.
- Drug listings do not have to be submitted unless there is a change.

5. NDC and drug listing questions- formulation changes: Mary Beth Kline
Do formulation changes (not dosage strength) require new NDC numbers to be assigned?

Meeting Discussion:

- It depends.
- Subject to own interpretation of whether you consider this a new product that needs to be tracked separately.

6. Annual DER re-registration – D&B issues. -Melissa A. Ignatowski
I would like to discuss if anything can be done with Dun & Bradstreet.

Every six months, D&B changes the information pertaining to my company's DUNS numbers. This happens EVERY TIME we have an Establishment Registration or GDUFA Self-ID filing. Correcting the information takes approximately four to six weeks! We have had this problem since 2010. Reaching a helpful individual at D&B is impossible because most employees appear oblivious to the fact that we use the DUNS numbers for our SPL filings and that we are NOT government contractors. Also, when we inquire as to how and why the information changes, we never get an answer.

My questions to the group are as follows:

- Do you know of a contact at D&B who fixes DUNS-number issues like this?
- If not, to whom can we file a grievance (as this problem is unacceptable)?
- Is anyone at the FDA (Lonnie?) aware of how difficult dealing with D&B is?

I sincerely appreciate any information you have that may alleviate our problem and frustration with D&B. I also apologize for the venting session.

Meeting Discussion:

- If possible, work through your own company's "relationship manager." This is much more productive than calling the DnB customer service.
- Process is pretty slow.
- We have worked with Ryan Paul at D&B in the past. We hope to be able to make some meaningful change.
- Per Lonnie: At this point, instead of reporting the issue to D&B directly, it may be best for the company to send an e-mail with a complete description of the issue to the SPL e-mail account and then I will forward that message to Dr. John Gardner who is the FDA liaison for D&B-related projects. Dr. Gardner can then contact D&B to report the issue and I will periodically follow up with Dr. Gardner.
- **Copy Pat on the email. Subject line: SPL DnB Feedback**

7. Is there any guidance around the style sheet requirements for SPL; during our qc process of SPLs, the product leads have comments on the content of SPL that cannot be changed because it's part of the style sheet or metadata requirements; there seems to be a lack in knowledge regarding the this technical piece of SPL conversions. (Janet Deluca –Genzyme)

Meeting Discussion:

- No. We get questions on this all the time. There are things that can't change.
- You can push back to FDA and educate them on the SPL stylesheet needs.

8. PDUFA approval letters for new drugs – there is a 14 day window to submit the SPL to the OC – there are times when it's very difficult to meet the 14 day timeline with the back and forth from the vendor and product leader as the SPL becomes final – we understand the 14 day timeline are calendar days – it would be beneficial to consider changing the 14 days from calendar to business days in light of the SPL process to to "ready for final submission to the OC". (Janet Deluca – Genzyme)

Meeting Discussion:

- They are calendar days.
- If you aren't launching immediately, you can submit with a future date.
- If you can't make the 14 days, then go back to the review division and get the OK from the review division.
- To prove that you met the 14 day submission, you could send CDER a link to the SPL – so that they know that it exists and where to find it in the eList system.
- PDP – only submit the outermost carton. Regs say "representative sample of labeling". FDA wants to limit the number of images that they are including.
- Multiple packaging sites for the same product – same label,

9. Bulk listing – how do we find out what all has been listed.
- Contact eDRLS staff and they will send you a list of all drug listings for a specific labeler code
 - If you have a single product, contact Lonnie.
10. What if the product doesn't have any active ingredients – lubricating jelly.
- Validation says that you need an active ingredient
 - Lubricating jelly is a device, you don't have to submit SPL – because not
 - Go through CDRH. Submit whatever they have for drug listing.
11. AOB/Walkins

REMINDERS:

- To accompany publication of the FDA's draft "Guidance for Industry – Electronic Submission of Lot Distribution Reports," an updated version of the SPL Implementation Guide/Validation Procedures document which includes a specific reference to the aforementioned guidance document has been posted: <http://www.fda.gov/downloads/ForIndustry/DataStandards/StructuredProductLabeling/UCM321876.pdf>.
- Sept 1, 2014 – Implementation of "Combination Product Type" data element for CDER-regulated products

Link to FAQs:

<http://www.fda.gov/CombinationProducts/AboutCombinationProducts/ucm101496.htm>

Definitions are available on the link from the SPL Resources page - SPL Terminology Files for Validation - [Combination Product Category Types](http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm) (XML and Excel): open the xml/excel file)
<http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>

- DER Annual reporting period: Must be submitted for 2015 between October 1 and December 31, 2014.